

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: John B. Harley, Judith Ann James, and Kenneth M. Kaufman

Serial No.: Divisional of 09/718,693 Art Unit: Not Yet Assigned

Filed: August 22, 2003 Examiner: Not Yet Assigned

For: *ASSAYS AND THERAPIES FOR LATENT VIRAL INFECTION*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including fifteen (15) pages of Form PTO-1449. All of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/718,693, filed November 22, 2000, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

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<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
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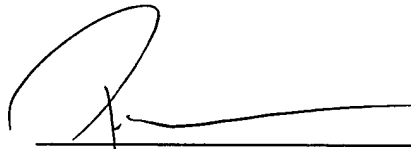
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Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



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Dated: August 22, 2003

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		Filing Date	August 22, 2003
		First Named Inventor	John B. Harley
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OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
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		ADELSTEIN, et al., <i>Nucl. Med. Biol.</i> 14: 165-169 (1987).	
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				Application Number		Divisional of 09/718,693	
				Filing Date		August 22, 2003	
				First Named Inventor		John B. Harley	
				Group Art Unit			
				Examiner Name			
Sheet	3	of	15	Attorney Docket Number		OMRF 177 DIV	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
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		BROWNING, et al., <i>J. Immunol.</i> 143: 1859-1867 (1989).	
		CALDERWOOD, et al., "Nucleotide sequence of the Shiga-like toxin genes of <i>Escherichia coli</i> ," <i>Proc. Natl. Acad. Sci. USA</i> 84: 4364-4368 (1987).	
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		DEACON, et al., "Frequency of EBV DNA Detection in Sjogren's Syndrome," <i>Am J. Med.</i> 92: 453-454 (1992).	
		DEBRUS, et al., "Varicella-zoster virus gene 63 encodes an immediate-early protein that is abundantly expressed during latency," <i>J. Virol.</i> 69: 3240-3245 (1995).	
		DEDRICK, et al., <i>Cancer Treat. Rep.</i> 62: 1-11 (1978).	

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		First Named Inventor	John B. Harley
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Sheet 4 of 15	Attorney Docket Number	OMRF 177 DIV	

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		DELEERS, et al., <i>FEBS Lett.</i> 160: 82-86 (1983).	
		DIENER, et al., "Specific Immunosuppression by Immunotoxins Containing Daunomycin," <i>Science</i> 231(4734): 148-150 (1986).	
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		DONAHUE, et al., <i>Arch. Int. Med.</i> 155: 1605-1609 (1995).	
		ELEK, et al., <i>Lancet</i> 1: 1-5 (1974).	
		ERTL, et al., "Physical and functional interaction of human cytomegalovirus DNA polymerase and its accessory protein (ICP36) expressed in insect cells," <i>J. Virol.</i> 66: 4126-33 (1992).	
		FERREL, et al., <i>J. Clin. Invest.</i> 67: 681-687 (1981).	
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		FINERTY, et al., "Protective Immunization Against Epstein-Barr Virus-Induced Disease in Cotton-top Tamarins Using the Virus Envelope glycoprotein gp340 Produced from a Bovine Papillomavirus Expression Vector," <i>J. Gen. Virol.</i> 73: 449-453 (1992).	

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		Filing Date	August 22, 2003
		First Named Inventor	John B. Harley
		Group Art Unit	
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Sheet 5 of 15	Attorney Docket Number	OMRF 177 DIV	

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		FOX, "Sjogren's Syndrome," <i>Current Opin. Rheum.</i> 7: 409-416 (1995).	
		FOX, et al., "Detection of Epstein-Barr Virus-Associated Antigens and DNA in Salivary Gland Biopsies from Patients with Sjogren's Syndrome," <i>J. Immunol.</i> 137: 3162-3168 (1986).	
		FOX, et al., "Potential Role of Epstein-Barr Virus in Sjogren's Syndrome and Rheumatoid Arthritis," <i>J. Rheumatol.</i> 19: 18-24 (1992).	
		GLASSY, et al., <i>J. Immunol. Methods</i> 81: 115 (1985).	
		GOODRICH, et al., <i>Ann. Intern. Med.</i> 118:173-178 (1993).	
		GRAY, et al., "Cloning, nucleotide sequence, and expression in <i>Escherichia coli</i> of the exotoxin A structural gene of <i>Pseudomonas aeruginosa</i> ," <i>Proc. Natl. Acad. Sci. USA</i> 81: 2645-2649 (1984).	
		GREENWOOD, et al., <i>Biochem. J.</i> 89: 114-123 (1963).	
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		GU, et al., "First EBV Vaccine Trial in Humans Using Recombinant Vaccinia Virus Expressing the Major Membrane Antigen," <i>Dev. Biol. Stand.</i> 84: 171-177 (1995).	
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		Filing Date	August 22, 2003
		First Named Inventor	John B. Harley
		Group Art Unit	
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		HAAHR, et al., "A Putative New Retrovirus Associated with Multiple Sclerosis and the Possible Involvement of Epstein-Barr Virus in This Disease," <i>Ann. N. Y. Acad. Sci.</i> 724: 148-156 (1996).	
		HALPERN, et al., <i>J. Nucl. Med.</i> 29: 1688-1696 (1988).	
		HARLEY & JAMES, "Epstein-Barr virus infection may be an environmental risk factor for systemic lupus erythematosus in children and teenagers," <i>Arthr. Rheum.</i> 42(8): 1782-1783 (1999).	
		HESLOP, et al., "Long-Term Restoration of Immunity Against Epstein-Barr Virus Infection by Adoptive Transfer of Gene-Modified Virus-Specific T Lymphocytes," <i>Nature Med.</i> 2: 551-555 (1996).	
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		HO, <i>Cytomegalovirus, biology and infection: current topics in infectious disease</i> Plenum Press: New York, pp. 105-118 (1982).	
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		HWANG, et al., <i>Cell</i> 48: 129-136 (1987).	
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		John B. Harley	
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Sheet	7	of	15

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		JAMES & HARLEY, "Linear Epitope Mapping of an Sm B/B' Polypeptide," <i>J. Immunol.</i> 148: 2074-2079 (1992).	
		JAMES, et al., "Immunoglobulin Epitope Spreading and Autoimmune Disease After Peptide Immunization: Sm B/B'-derived PPPGMRPP and PPPGIRGP Induce Spliceosome Autoimmunity," <i>J. Exp. Med.</i> 181: 453-461 (1995).	
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		KOHLER & MILSTEIN, <i>Nature</i> 256: 495-497 (1975).	
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		LEVITSKAYA, "Inhibition of Antigen Processing by the Internal Repeat Region of the Epstein-Barr Virus Nuclear Antigen-1," <i>Nature</i> 375:685-688 (1995).	
		LONGNECKER & KIEFF, "A second Epstein-Barr virus membrane protein (LMP2) is expressed in latent infection and colocalizes with LMP1," <i>J. Virol.</i> 64: 2319-2326 (1990).	
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		MERRIFIELD, <i>J. Am. Chem. Soc.</i> 85: 2149 (1964).	
		MIYASHITA, et al., "Identification of the site of Epstein-Barr virus persistence in vivo as a resting B cell," <i>J. Virol.</i> 71: 4882-4891 (1997).	
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		Applicant Number	Divisional of 09/718,693
		Filing Date	August 22, 2003
		First Named Inventor	John B. Harley
		Group Art Unit	
		Examiner Name	
Sheet 11 of 15	Attorney Docket Number	OMRF 177 DIV	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		NEWKIRK, et al., "Detection of Cytomegalovirus, Epstein-Barr Virus and Herpes Virus-6 in Patients with Rheumatoid Arthritis With or Without Sjogren's Syndrome," <i>Br. J. Rheum.</i> 33:317-322 (1994).	
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		QUADRI, et al., <i>Nucl. Med. Biol.</i> 20: 559-570 (1993).	

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		Applicant Number	Divisional 109/718,693
		Filing Date	August 22, 2003
		First Named Inventor	John B. Harley
		Group Art Unit	
		Examiner Name	
Sheet 12 of 15	Attorney Docket Number	OMRF 177 DIV	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials ⁴	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		REUSSER, et al., <i>J. Infect. Dis.</i> 166: 473-479 (1992).	
		RICKINSON & KIEFF, "Epstein-Barr virus" in <i>Fields Virology</i> , Lippincott-Raven, pp. 2397-2446 (1996).	
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		SALACINSKI, et al., <i>Anal. Biochem.</i> 117: 136-146 (1981).	
		SCHMIDT, et al., " <i>Proc. Natl. Acad. Sci. USA</i> 88(21): 9478-9482 (1991).	

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		Application Number	Divisional of 09/718,693
		Filing Date	August 22, 2003
		First Named Inventor	John B. Harley
		Group Art Unit	
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Sheet 13 of 15	Attorney Docket Number	OMRF 177 DIV	

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		SCOTET, et al., <i>J. Exp. Med.</i> 184: 1771-1780 (1996).	
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		Filing Date	August 22, 2003
		First Named Inventor	John B. Harley
		Group Art Unit	
		Examiner Name	
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		SUN, et al., <i>Hybridoma</i> 5(Supp1): S17 (1986).	
		SUNDBERG, et al., <i>Nature</i> 250: 587-588 (1974).	
		TAKEI, et al., <i>Int. Immunol.</i> 9: 739-743 (1997).	
		TAN, <i>Rev. Inf. Dis.</i> 1: 997-1006 (1979).	
		TATEISHI, et al., "Spontaneous Production of Epstein-Barr Virus by B Lymphoblastoid Cell Lines Obtained from Patients with Sjogren's Syndrome," <i>Arthritis Rheum.</i> 36:827-835 (1993).	
		THORLEY-LAWSON, et al., "Epstein-Barr virus and the B cell: that's all it takes," <i>Trends in Microbiology</i> 4(5): 204-208 (1996).	
		TODA, et al., "Sjogren's syndrome (SS) and Epstein-Barr virus (EBV) reactivation," In <u>Lacrimal Gland, Tear Film, and Dry Eye Syndrome</u> , (D.A. Sullivan, ed.) pp. 647-650 (Plenum Press, New York 1994).	
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		VENABLES, et al., "Persistence of Epstein-Barr Virus in Salivary Gland Biopsies from Healthy Individuals and Patients with Sjogren's Syndrome," <i>Clin. Exp. Immunol.</i> , 75:359-364 (1989).	
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		VENABLES, et al., <i>Arthr. Rheum.</i> 24: 1459-1468 (1981).	
		VRISENDORP, et al., "Radioimmunoglobulin therapy" in <i>High Dose Cancer Therapy</i> (Armitage, et al. eds) Williams & Wilkins: Baltimore, pp. 84-123 (1992).	
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		WANG, et al., <i>Radiat. Res.</i> 141: 292-302 (1995).	
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		WATSON, et al., "Certain Properties Make Substances Antigenic," in <i>Molecular Biology of the Gene</i> , Fourth Edition, page 836, paragraph 3, (The Benjamin/Cummings Publishing Company, Menlo Park, 1987).	
		WHITLEY, "Herpes Simplex viruses" in <i>Field's Virology</i> Lippincott-Raven, pp. 2297-2330 (1996).	

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